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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/688,665	10/17/2003	Gary F. Gerard	TI-0028	7596

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Transgenomic Inc.  
12325 Emmet Street  
Omaha, NE 68164

EXAMINER

PATTERSON, CHARLES L JR

ART UNIT PAPER NUMBER

1652

DATE MAILED: 03/02/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

10/688,665

Applicant(s)

GERARD ET AL.

Examiner

Charles L. Patterson, Jr.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 12 December 2003 and 05 January 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-12 is/are pending in the application.
- 4a) Of the above claim(s) 11 and 12 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 4-8 is/are allowed.
- 6) ☒ Claim(s) 1-3,9 and 10 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 17 October 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

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Applicant's election with traverse of Group I, claims 1-10 in the reply filed on 1/6/06 is acknowledged. The examiner agrees that he inadvertently left out claim 10 and that this claim should be a part of Group I. The traversal is on the ground(s) that the MPEP states that invention must be a serious burden upon the examiner if restriction is not required and that is not present here; that "the same protein element, i.e., an isolated CEL II endonuclease enzyme" is contained in both Group I and II; and that "an analysis of double-stranded DNA contacted with CEL II would inherently detect mismatches in the DNA". This is not found persuasive because Group I deals with the separation and/or purification of CEL I from CEL II whereas the method and kit of group II deals with a particular use of CEL II. While it is agreed that CEL II is found in both groups, this is not a reason to combine them. The previous restriction requirement is deemed to be valid and to meet the requirement of the MPEP, and furthermore it is maintained that there would be a serious burden on the examiner to examine both groups. Group I only requires that a method for separating CEL I and CEL II be found and does not in any way require that the detection of mismatches with CEL II be searched for.

The requirement is still deemed proper and is therefore made FINAL.

Claims 11-12 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 1/6/06.

The disclosure is objected to because of the following informalities:

On page 9, last paragraph, it is stated that "Figure 4 shows that...CEL II migrates as two bands at 14 and 28 kDA in SDS-PAGE". Looking at Figure 4,

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it is seen that there is a broad band corresponding at about 50 kDa and another band corresponding to about 57 kDa. There is not seen to be bands of CEL II corresponding to 14 and 28 kDa in this figure.

Appropriate correction is required.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-3 and 9-10 are rejected under 35 U.S.C. 102(e) as being anticipated by Yeung (C). Yeung teach the purification of CEL I and CEL II and their separation from each other in Example 4. It is maintained that the specific activity of CEL II, as in claim 10, is over 10,000,000 because the specific activity in Table I of the reference is  $3.1 \times 10^7$  and CEL II was separated from this fraction by SDS PAGE and had activity.

Claims 1 and 9 are rejected under 35 U.S.C. 102(b) as being anticipated by either of Oleykowski, et al. (BC) or Yang, et al. (BE). The instant references teach a "purified and isolated CEL II or CEL I" enzyme. The refer-

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ences teach the purification of what is called CEL I, which is either "CEL II or CEL I". It is pointed out that to be "purified and isolated" does not require any level of purification or isolation but rather any degree will meet the claim requirements. Claim 9 is drawn to "[a] composition comprising isolated CEL II endonuclease". Since it has been shown that the preparations of the instant references inherently includes CEL II, these references meet the requirements of the instant claim.

Claims 4-8 are allowed. The examiner has been unable to find anything in the prior art that would anticipate or make obvious the use of heparin affinity chromatography to separate CEL I and CEL II.

It is noted that reference AA cited in the PTO-1449 filed 12/12/03 is a patent to Yeung, but rather an unrelated patent to Alt, as now noted on the PTO-1449. Apparently reference A, listed on the enclosed PTO-892, was intended by applicants. Yeung (B) is cited as of interest.

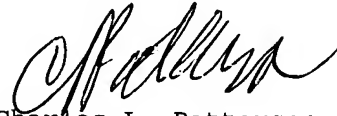
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Charles L. Patterson, Jr., PhD, whose telephone number is 571-272-0936. The examiner can normally be reached on Monday - Friday from 7:30 to 4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy, can be reached on 571-272-0928. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status informa-

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tion for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Charles L. Patterson, Jr.  
Primary Examiner  
Art Unit 1652

Patterson  
February 23, 2006